Vaccine Storage & Handling and Administration

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July 2015

Vaccine Storage & Handling Toolkit

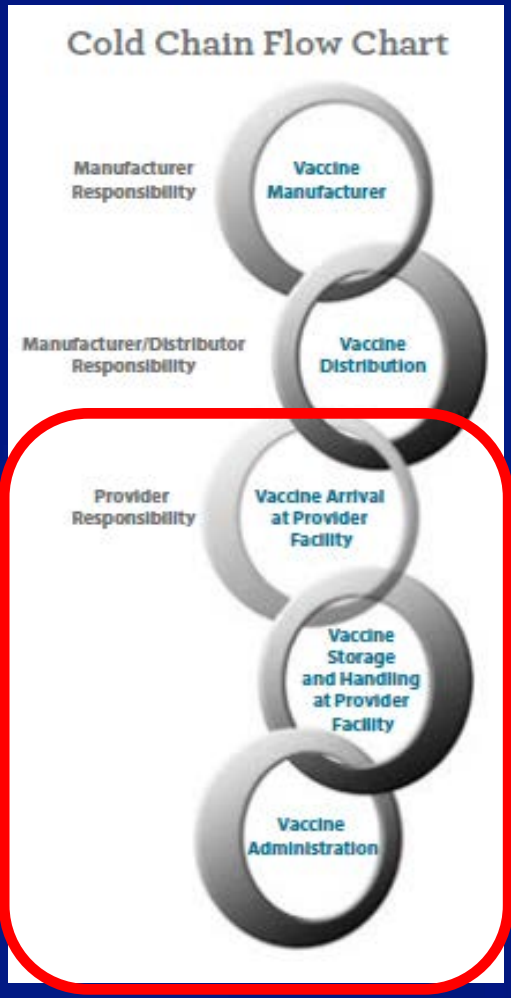
May 2014

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/vaccines/recs/storage/toolkit/default.htm

Vaccine S&H Cold Chain

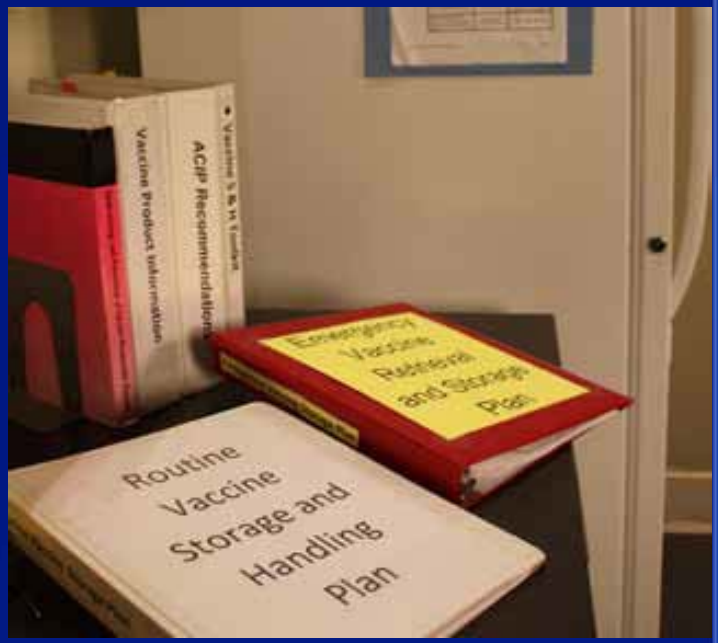
- Vaccines must be stored properly from the time they are manufactured until they are administered
- Shared responsibility among manufacturers, distributors, public health staff, and healthcare providers
- Provider cold chain management
  - Trained personnel
  - Appropriate equipment
  - Efficient vaccine management



www.cdc.gov/vaccines/recs/vac-admin/providers-role-vacc-admin-storage.htm

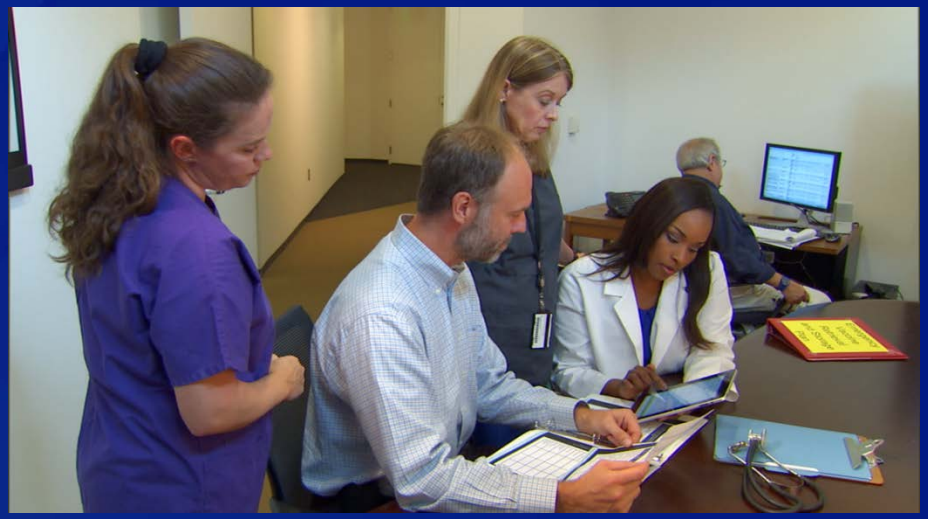
Vaccine Storage and Handling Plans

- Develop and update plans annually
  - Routine Plan
  - Emergency Plan
- Keep plans near storage unit(s)
  - Ensure staff know where to find plans and are familiar with them
  - Ensure custodial /security staff are familiar with emergency notification procedures



Staff Training and Education

- Designate a primary coordinator and at least one alternate (back-up) coordinator
- Coordinators should be fully trained in routine and emergency policies and procedures
- A physician partner or member of management should be directly involved with responsible clinical staff



Vaccine Storage and Handling Training

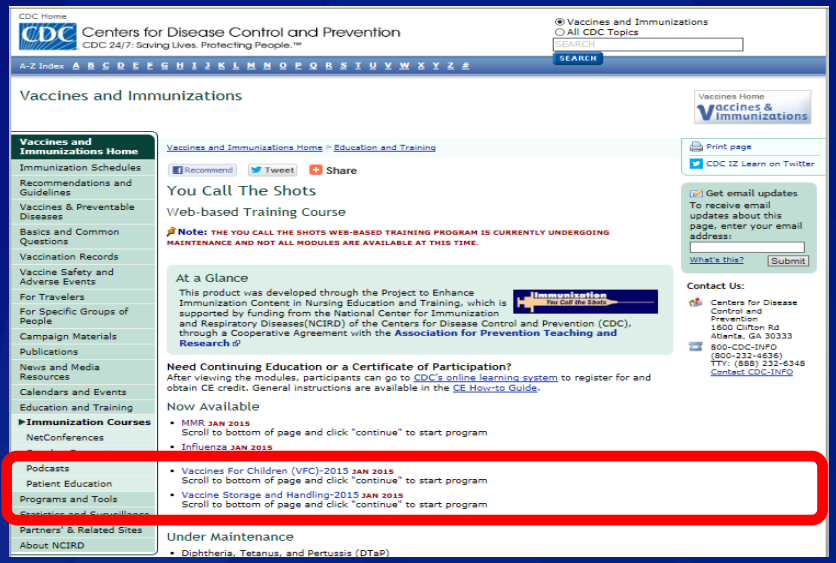
- All staff who receive deliveries, handle or administer vaccines, and have access to vaccine storage units should be familiar with storage and handling policies and procedures

- Storage and handling training should:
  - Be part of new employee orientation
  - Be annual training for all staff involved in these activities
  - Occur whenever recommendations are updated and when new vaccines are added

Training Resources

You Call the Shots

www.cdc.gov/vaccines/ed/youcalltheshots.htm



Keys to Storing and Handling Your Vaccine Supply

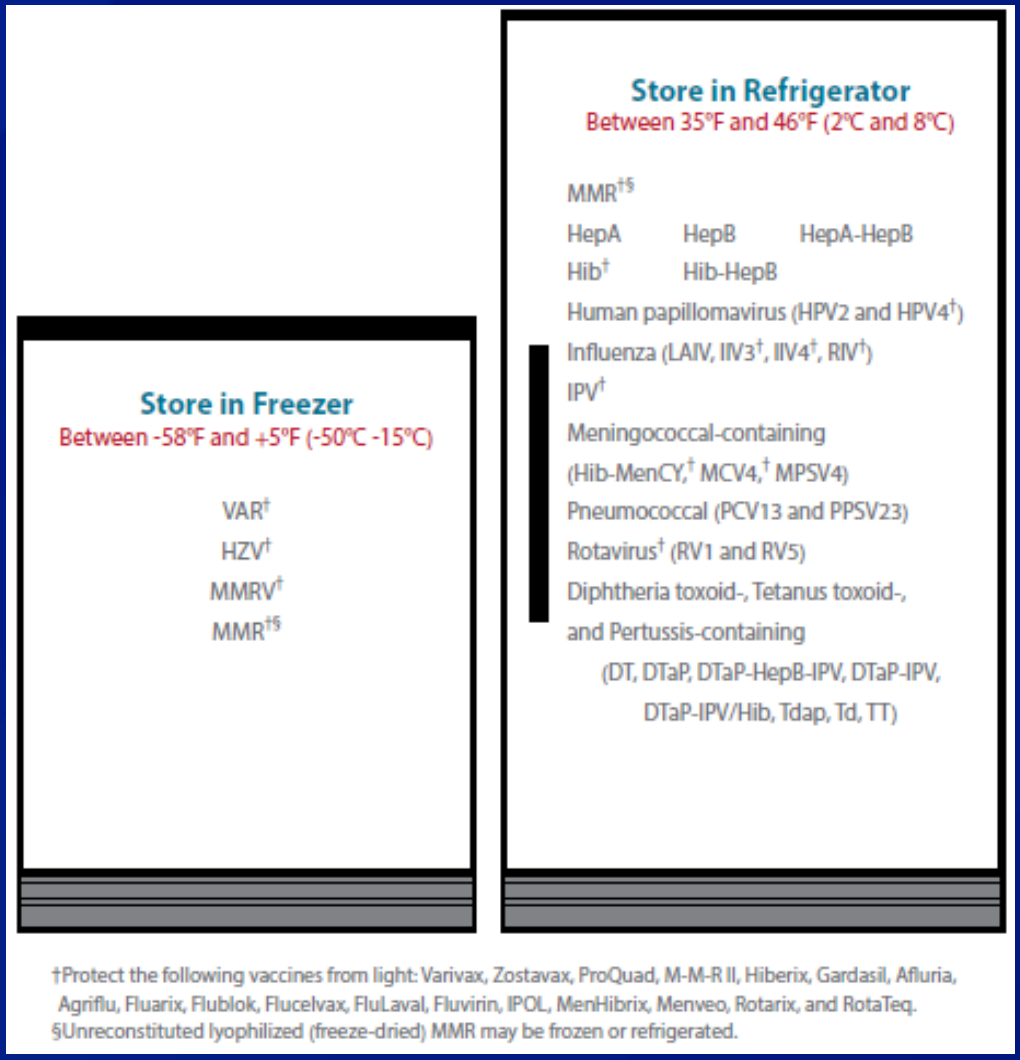
http://www2.cdc.gov/vaccines/ed/shvideo/

Vaccine Deliveries

- Arrange deliveries when vaccine coordinator or alternate is on duty and notify them when delivery arrives
- Avoid having people accept deliveries who may not understand the importance of storage at appropriate temperatures upon arrival
- Examine vaccine deliveries:
  - Container
  - Contents
  - Shipping temperature monitors/indicators
- If there are concerns:
  - Label vaccines "Do NOT Use,"
  - Store under appropriate conditions, separate from other vaccines
- Consult immunization program, distributor, and/or vaccine manufacturer for guidance

Vaccine Storage Equipment

- CDC recommends stand-alone or pharmacy grade/purpose-built units



Vaccine Storage Equipment

- If existing equipment is a household, combination refrigerator/freezer, CDC recommends using only the refrigerator compartment for refrigerated vaccines

Combination refrigerator/freezer

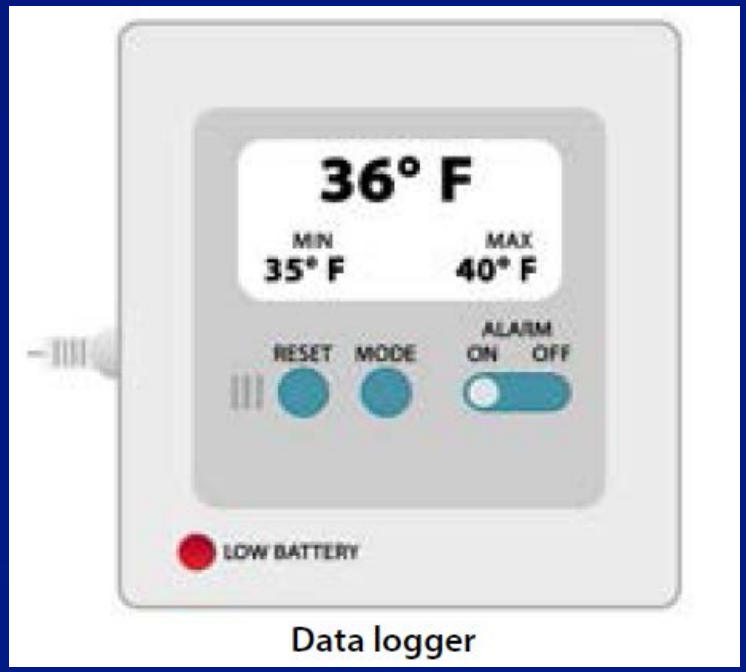
Dormitory-style NOT Allowed for VFC Vaccines or Recommended for ANY Vaccine Storage

Temperature Monitoring Equipment

- **CDC recommends:**
  - Use calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration)
  - Use digital data loggers for continuous temperature monitoring
  - Staff should be trained and understand how to set up, read, and analyze temperature data provided by the data logger

Temperature Monitoring Equipment

- **CDC recommends these characteristics:**
  - Digital display on outside of unit
  - Detachable probe in a thermal buffer
  - Alarm to alert out-of-range temperatures
  - Accuracy within +/-1°F (+/-.5°C)
  - Low battery indicator



Data logger

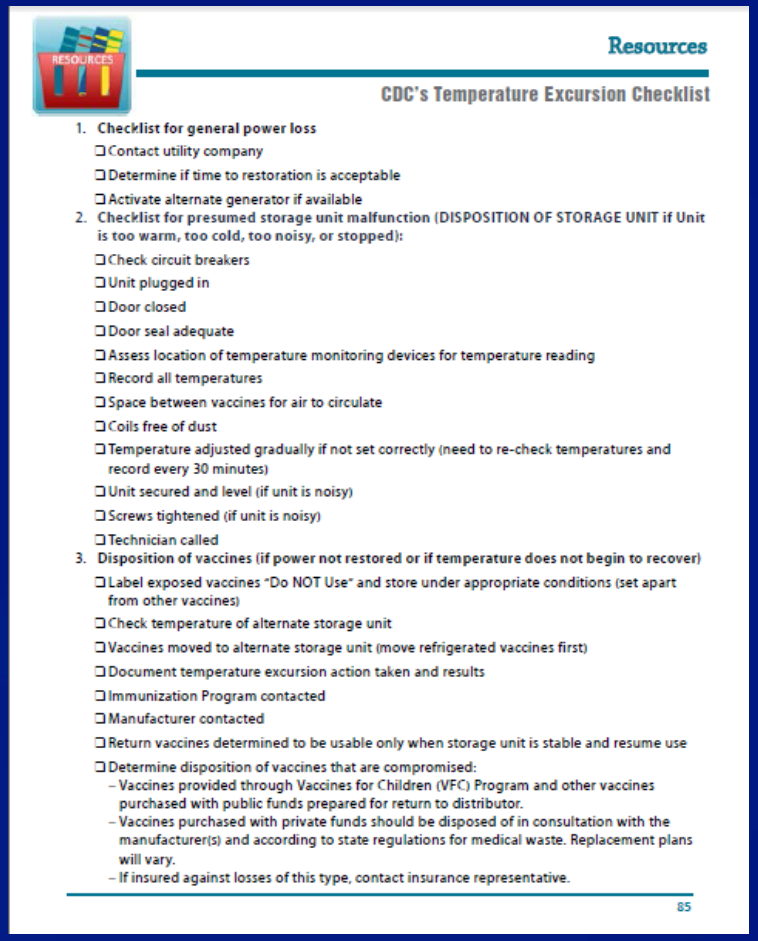
  - Continuous monitoring and recording capabilities
  - Display of current, minimum, and maximum temperatures if using a digital data logger

Temperature Monitoring

- Review and record temperatures in both freezer and refrigerator units 2 times each day, once in the morning and once before leaving at the end of the workday
- Post temperature log on the door of each storage unit
- If using a continuous temperature monitor, download temperature data and review weekly
- Keep temperature logs (hard copies and downloaded data) 3 years or according to individual state record retention requirements

Temperature Excursion

- **If stored vaccines have been exposed to temperatures outside recommended ranges**
  - Store the vaccines properly
  - Separate from other vaccine supplies
  - Mark "Do NOT Use"
  - Contact immunization program, vaccine manufacturer(s), or both for guidance



Resources

CDC's Temperature Excursion Checklist

1. **Checklist for general power loss**
   - ❑ Contact utility company
   - ❑ Determine if time to restoration is acceptable
   - ❑ Activate alternate generator if available
2. **Checklist for presumed storage unit malfunction (DISPOSITION OF STORAGE UNIT if Unit is too warm, too cold, too noisy, or stopped):**
   - ❑ Check circuit breakers
   - ❑ Unit plugged in
   - ❑ Door closed
   - ❑ Door seal adequate
   - ❑ Assess location of temperature monitoring devices for temperature reading
   - ❑ Record all temperatures
   - ❑ Space between vaccines for air to circulate
   - ❑ Coils free of dust
   - ❑ Temperature adjusted gradually if not set correctly (need to re-check temperatures and record every 30 minutes)
   - ❑ Unit secured and level (if unit is noisy)
   - ❑ Screws tightened (if unit is noisy)
   - ❑ Technician called
3. **Disposition of vaccines (if power not restored or if temperature does not begin to recover)**
   - ❑ Label exposed vaccines "Do NOT Use" and store under appropriate conditions (set apart from other vaccines)
   - ❑ Check temperature of alternate storage unit
   - ❑ Vaccines moved to alternate storage unit (move refrigerated vaccines first)
   - ❑ Document temperature excursion action taken and results
   - ❑ Immunization Program contacted
   - ❑ Manufacturer contacted
   - ❑ Return vaccines determined to be usable only when storage unit is stable and resume use
   - ❑ Determine disposition of vaccines that are compromised:
     - Vaccines provided through Vaccines for Children (VFC) Program and other vaccines purchased with public funds prepared for return to distributor.
     - Vaccines purchased with private funds should be disposed of in consultation with the manufacturer(s) and according to state regulations for medical waste. Replacement plans will vary.
     - If insured against losses of this type, contact insurance representative.

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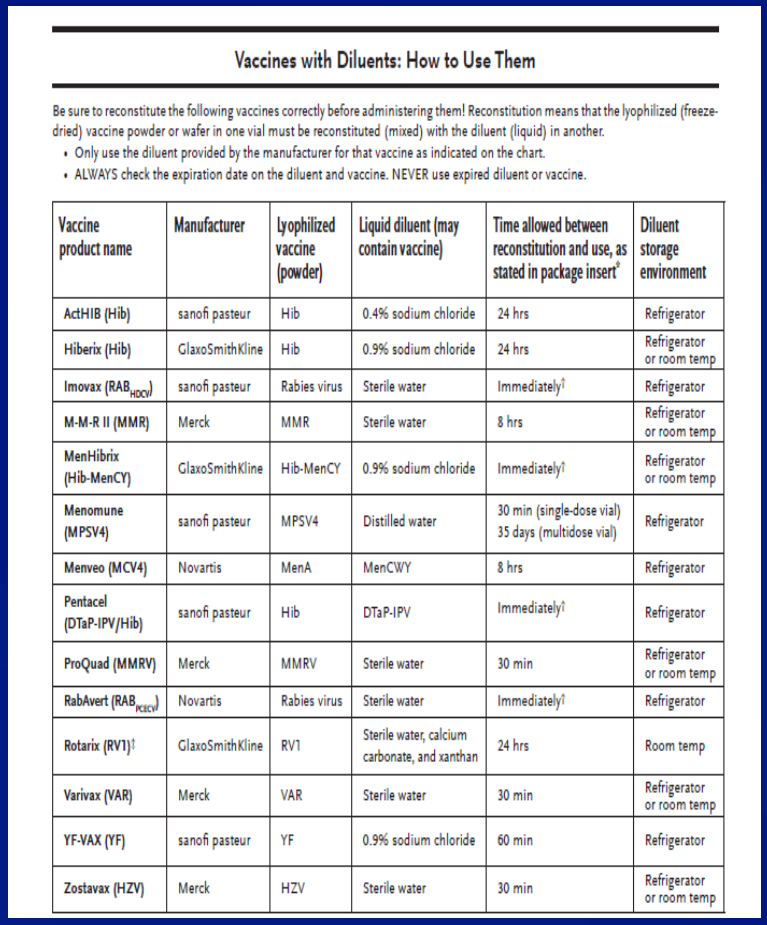
www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

Vaccine and Diluent Placement and Labeling

- Store vaccines away from wall, coils, cooling vents, top shelf, ceiling, door, floor, and back of unit
- Keep vaccines and diluents in original packaging with lids on to maintain temperature, protect from light, and prevent errors
- Stack in rows 2-3 inches apart with same type of vaccine and diluent
- Use uncovered storage containers to organize vaccines and diluents
- Do not store vaccines in storage unit doors or in deli, vegetable, or fruit crisper drawers
- Store pediatric and adult vaccines on different shelves
- Use labels with vaccine type, age, and gender indications or color coding
- Do not store sound-alike or look-alike vaccines next to each other
- Follow VFC guidelines for storing these vaccines if you also store vaccines purchased with private fund

Diluent Storage

- Store diluent as directed in manufacturer's product information
- Store refrigerated diluent with corresponding vaccine (these diluents may contain vaccine antigen)
- Never store diluents in the freezer
- Label diluent to avoid inadvertent use of the wrong diluent when reconstituting a vaccine



Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert[2]	Diluent storage environment
ActHIB (Hib)	sanofi pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB_{HDCV})	sanofi pasteur	Rabies virus	Sterile water	Immediately[†]	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
MenHibrix (Hib-MenCY)	GlaxoSmithKline	Hib-MenCY	0.9% sodium chloride	Immediately[†]	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (multidose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	Hib	DTaP-IPV	Immediately[†]	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB_{PCECV})	Novartis	Rabies virus	Sterile water	Immediately[†]	Refrigerator
Rotarix (RV1)[‡]	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	sanofi pasteur	YF	0.9% sodium chloride	60 min	Refrigerator
Zostavax (HZV)	Merck	HZV	Sterile water	30 min	Refrigerator or room temp

www.immunize.org/catg.d/p3040.pdf

Preventive Measures

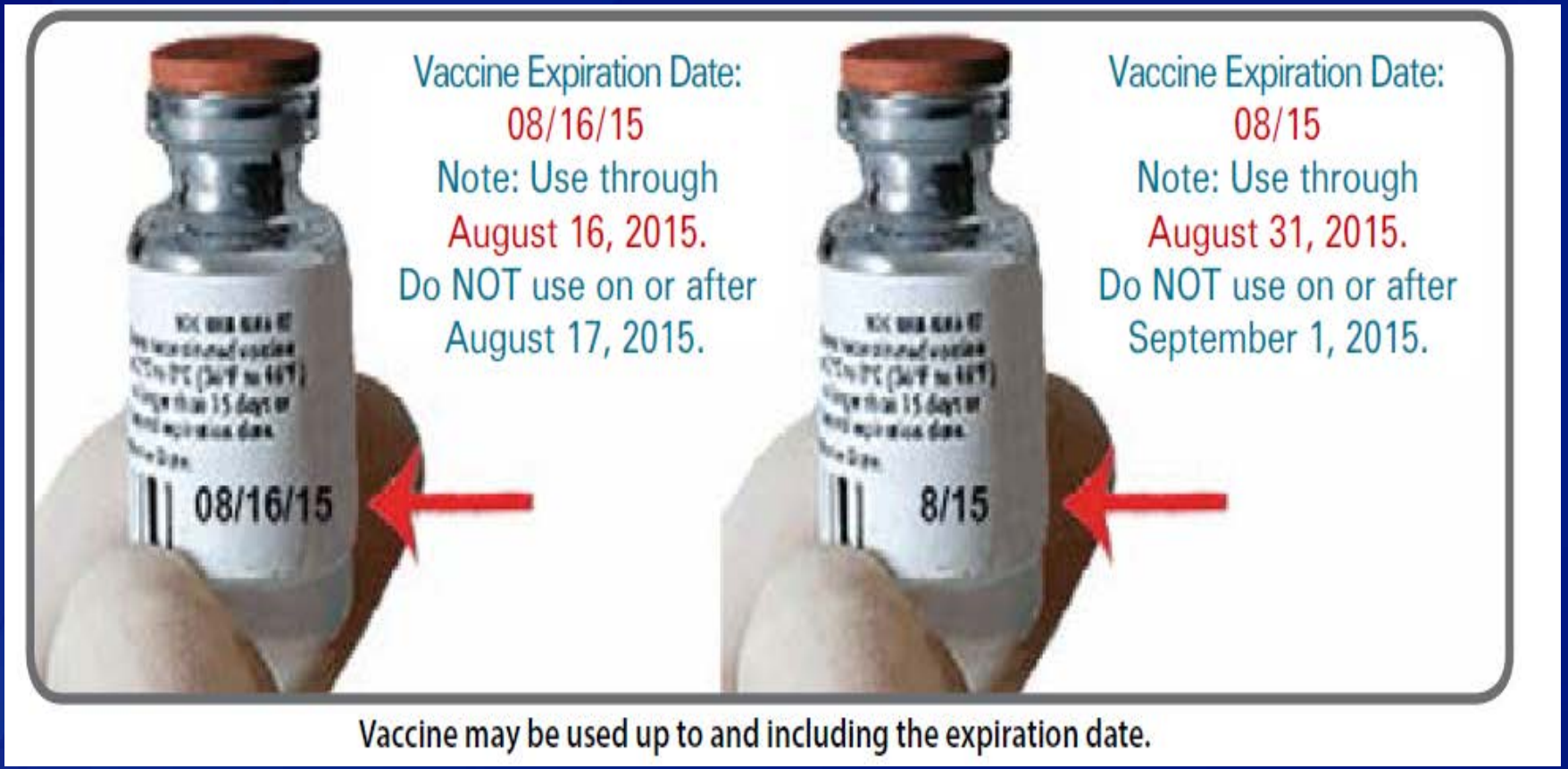
- Plug unit directly into wall; do NOT use multi-outlet power strip
- Do NOT use power outlets with built-in circuit switchers
- Do NOT use power outlets that can be activated by a wall switch
- Plug only one unit into an outlet
- Use a plug guard or safety-lock plug
- Install a temperature alarm
- Label circuit breakers and electrical outlets
- Post warning signs that include emergency contact information
- Use water bottles in refrigerator and frozen water bottles in freezer to maintain temperature
- Perform daily inspection of storage unit(s)
- If other biologics must be stored in the same unit, store them BELOW the vaccines to avoid contamination
- Never store food and beverages in the same unit with vaccines
- Take immediate corrective action when there is a problem

Vaccine and Diluent Inventory Control

- Conduct a monthly vaccine and diluent inventory
- Order vaccine based on
  - Projected demand
  - Storage capacity
  - Current supply
- Avoid overstocking

Vaccine Expiration Dates

- At least 1 time each week and each time vaccines are delivered, check and arrange vaccines and diluents in storage unit according to expiration dates



Exceptions to Vaccine Expiration Dates

- **Reconstitution**
  - Once a lyophilized vaccine is reconstituted, there is a limited timeframe in which the vaccine can be used

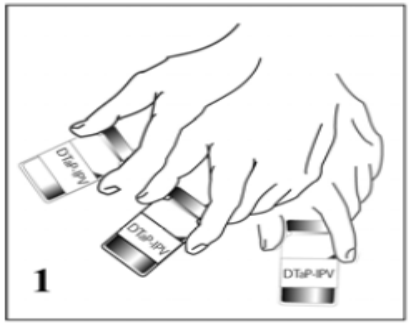


Figure 1
Gently shake the vial of DTaP-IPV component.

Figure 2
Withdraw the entire liquid content.

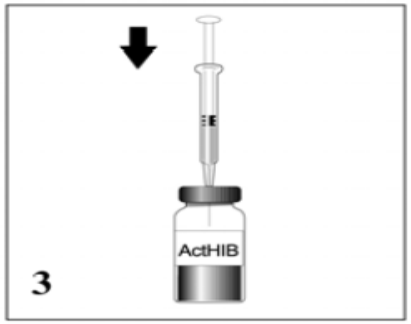


Figure 3
Insert the syringe needle through the stopper of the vial of lyophilized ActHIB vaccine component and inject the liquid into the vial.

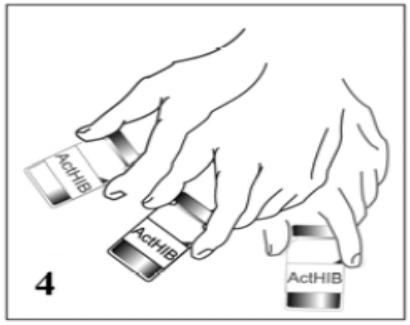


Figure 4
Swirl vial gently.

Exceptions to Vaccine Expiration Dates

- **Reconstitution**
  - Once a lyophilized vaccine is reconstituted, there is a limited timeframe in which the vaccine can be used

Exceptions to Vaccine Expiration Dates

- **Multidose vials (MDVs)**
  - Most MDVs may be used until the expiration date on the vial unless contaminated or compromised in some way. Some MDVs have a specified timeframe for use once the vial is entered

2.2 Administration Instructions

Shake well before administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Attach a sterile needle to the prefilled syringe and administer intramuscularly.

For the multi-dose vial, use a sterile needle and sterile syringe to withdraw the 0.5-mL dose from the multi-dose vial and administer intramuscularly. A sterile syringe with a needle bore no larger than 23 gauge is recommended for administration. It is recommended that small syringes (0.5 mL or 1 mL) be used to minimize any product loss. Use a separate sterile needle and syringe for each dose withdrawn from the multi-dose vial.

Between uses, return the multi-dose vial to the recommended storage conditions, between 2° and 8°C (36° and 46°F). Do not freeze. Discard if the vaccine has been frozen. Once entered, a multi-dose vial, and any residual contents, should be discarded after 28 days.

Exceptions to Vaccine Expiration Dates

- **Manufacturer shortened expiration date**
  - If vaccine has been exposed to inappropriate storage conditions, potency may be reduced before the expiration date. The manufacturer may shorten the expiration date

Exceptions to Vaccine Expiration Dates

- When vaccines must be used prior to the expiration date on the label, this is referred to as the "beyond use date" or "BUD
- The "BUD" (date and/or time) should be noted on the label along with the initials of the person changing the date/time

Vaccine Transport

- **CDC recommends:**
  - Have vaccines delivered directly to an off-site/satellite facility
  - If vaccines must be transported to off-site/ satellite facility, limit amount transported to what is needed for that workday
  - Transport and workday should total no more than **8 hours**
  - Transport using a portable refrigerator/freezer or qualified container and pack-out with calibrated, continuous temperature monitoring device

Vaccine Preparation

- Only open a single-dose vial when ready to use. Once protective cap is removed, vaccine should be used. If not used, it should be discarded at end of workday

Vaccine Preparation

- Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), vaccine should be used or discarded at end of workday

Vaccine Preparation

- **CDC recommends:**
  - Do not predraw vaccine:
    - Increases risk for administration errors
    - Wasted vaccine
    - Possible bacterial growth in vaccines that do not contain a preservative
    - Administration syringes not designed for storage

  - Consider using manufacturer-filled syringes for large immunization events because they are designed for both storage and administration
  - Draw up vaccines only at time of administration and discard if not used by end of day
  - Only administer vaccines that you have prepared

Vaccine Disposal

- Consult your immunization program or vaccine manufacturer regarding returnable vaccines and regarding state guidelines for disposal of medical waste

Vaccine Administration

Vaccine Administration

- Key to ensuring vaccination is as safe and effective as possible
- Incorporate
  - Professional standards for medication administration
  - Manufacturer's vaccine-specific guidelines
  - Evidence-based safe injection practices on CDC's Injection Safety Information for Providers webpage

www.cdc.gov/injectionsafety/providers.html

Staff Training and Education

- **Before administering vaccines, all personnel who administer vaccines should**
  - Receive competency-based training
  - Have knowledge and skills validated
- **Integrate competency-based training into**
  - New staff orientation
  - Annual education requirements
- **Ongoing education**
  - When vaccine administration recommendations are updated
  - When new vaccines are added to the inventory

www.eziz.org/assets/docs/IMM-694.pdf

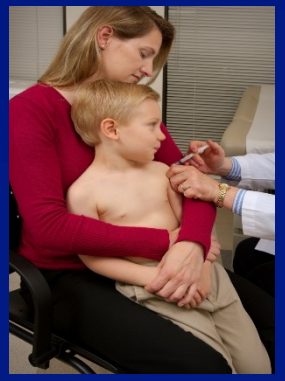
Patient Care Before Administering Vaccines

- Obtain complete immunization history at every healthcare visit
  - Accept only written, dated records (exception influenza and PPSV23 self-report)
  - Use recommended schedule to determine vaccines needed based on age, medical condition, and risk factors
- Screen for contraindications and precautions prior to administering any vaccine(s)
- Discuss vaccine benefits and risks and vaccine-preventable disease risks using VISs and other reliable resources
- Provide after-care instructions

www.immunize.org/catg.d/p4060.pdf
www.immunize.org/catg.d/p4065.pdf
http://publichealth.lacounty.gov/ip/immunization/parents/comfort-bethereEpdf

Positioning and Comforting Restraint

- Encourage parent/guardian to hold child
- Sitting, rather than lying down
- Be aware of syncope (fainting)
  - Have patient seated or lying down during vaccination
  - Be aware of symptoms that precede syncope
  - If patient faints, provide supportive care and protect patient from injury
  - Observe patient (seated or lying down) for at least 15 minutes after vaccination



Procedural Pain Management

- **Evidence-based strategies to ease pain**
  - Breastfeeding
  - Sweet tasting solutions
  - Injection technique (aspiration may increase pain)
  - Order of injections (administer most painful vaccine last)
  - Tactile stimulation (rub/ stroke near injection site prior to and during injection
  - Distraction
  - Topical anesthetic

Infection Control

- **Hand hygiene should be performed**
  - Before vaccine preparation
  - Between patients
  - Any time hands become soiled
- **Gloves are not required when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on hands**
  - If gloves are worn, they should be changed
  - Hand hygiene performed between patients

Vaccine Preparation

- Use a separate 1-mL or 3-mL sterile syringe for each injection
- Select a separate sterile needle for each injection based on route, size of individual, and injection technique
- Inspect vaccine and diluent vials for damage or contamination
- Check the expiration dates on the syringe, needle, vaccine, and diluent
- Use only the manufacturer supplied diluent to reconstitute a vaccine
- Agitate the vial to thoroughly mix the vaccine
- Inspect the vaccine for discoloration, precipitate, and if it is resuspended

Vaccine Preparation "Nevers"

- Never combine vaccines into a single syringe except when specifically approved by the FDA and packaged for that specific purpose
- Never transfer vaccine from one syringe to another
- Never draw partial doses of vaccine from separate vials to obtain a full dose

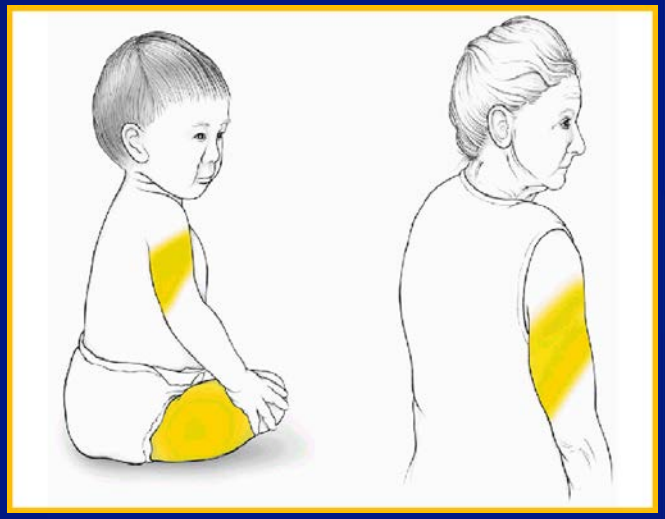
Route and Site

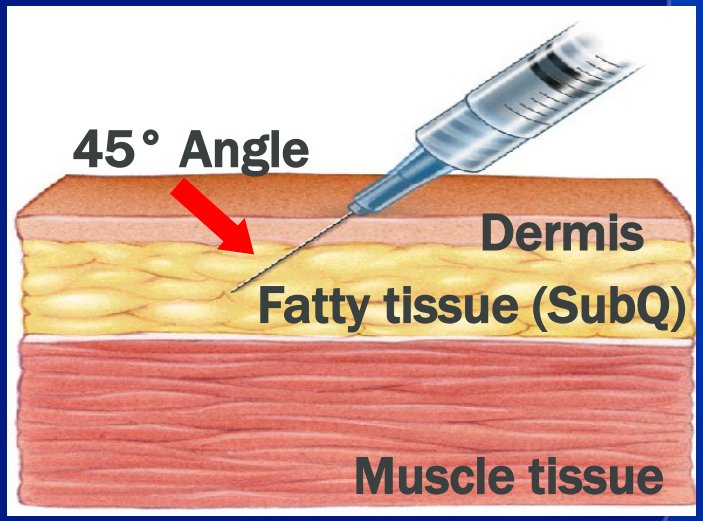
- Oral (PO)
  - Administer liquid slowly down one side of the inside cheek (between the cheek and gum) toward the back of infant's mouth

- Nasal (NAS)
  - LAIV is the only vaccine administered by the intranasal route
  - Insert the tip of the sprayer and spray half the dose in one nostril then remove the dose divider clip and administer the other half-dose in the other nostril

Subcutaneous (subcut) Route

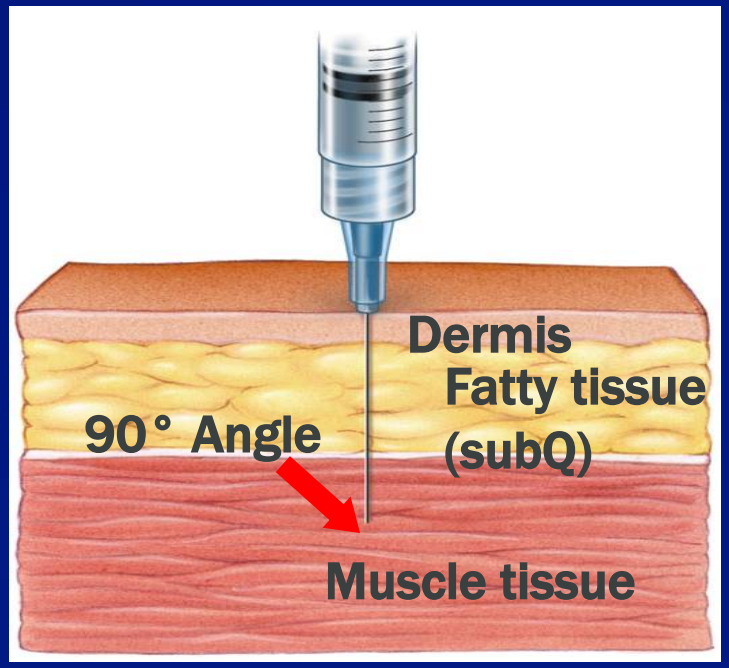
- **Site**
  - Thigh for infants younger than 12 months of age
  - Upper outer triceps of arm for children older than 12 months and adults (can be used for infants if necessary)
- **Needle gauge and length**
  - 23- to 25-gauge needle, 5/8- inch
  -
- **Technique**
  - To avoid reaching the muscle, pinch up the fatty tissue, insert the needle at a 45° angle and inject the vaccine into the tissue





Intramuscular (IM) Route

- Spread the skin of the site taut between the thumb and forefinger, isolating the muscle
- Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle
- Insert the needle fully into the muscle at a 90° angle and inject



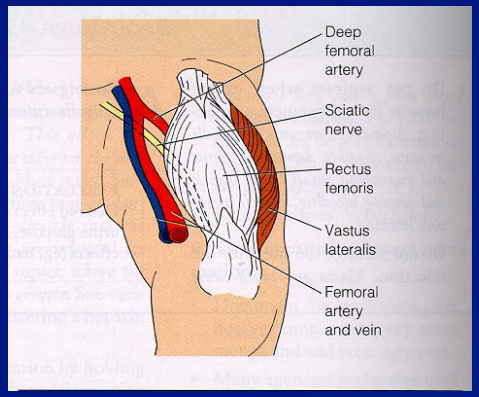
Aspiration is NOT required

Intramuscular (IM) Route Infants 12 Months and Younger

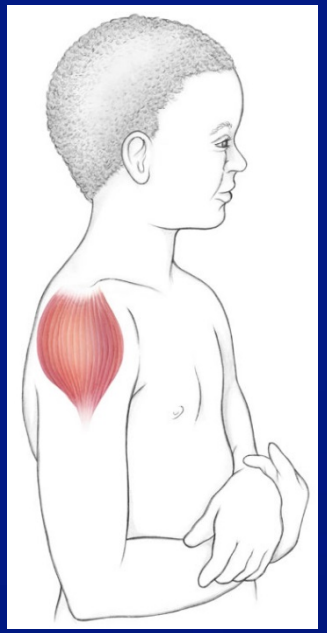
- **Site**
  - Vastus lateralis muscle (anterolateral thigh)
- **Needle gauge and length**
  - 22- to 25-gauge
  - Neonates and preterm infants: 5/8-inch 5/8-inch needle is adequate if the skin is stretched flat between thumb and forefinger
  - 1 month and older: 1-inch

Intramuscular (IM) Route 1 Year through 2 Years

- **Site**
  - Vastus lateralis muscle (anterolateral thigh) is preferred
  - Deltoid muscle (upper arm) may be used if the muscle mass is adequate

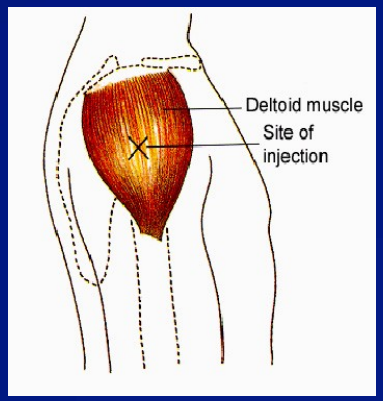


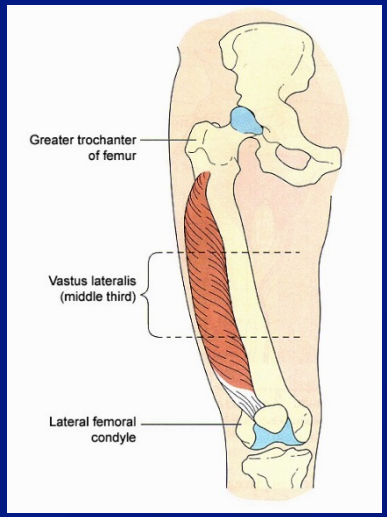
- **Needle gauge and length**
  - 22- to 25-gauge
  - 5/8 to 1-inch 5/8-inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger



Intramuscular (IM) Route 3 through 18 Years

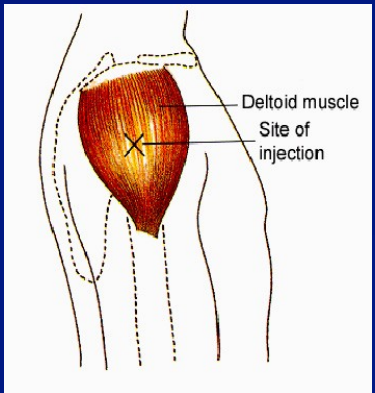
- **Site**
  - Deltoid muscle (upper arm) is preferred
  - Vastus lateralis muscle (anterolateral thigh) may be used
- **Needle gauge and length**
  - 22- to 25- gauge
  - 5/8 to 1-inch
- **Most young children in this age range require a 5/8 or 1-inch needle**
  - 5/8-inch needle is adequate only for the deltoid muscle and only if the skin is stretched flat between thumb and forefinger
- **Older children and adolescents require a 1-inch needle**

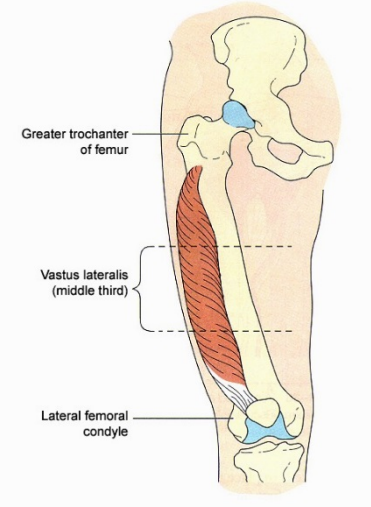




Intramuscular (IM) Route Adults 19 Years and Older

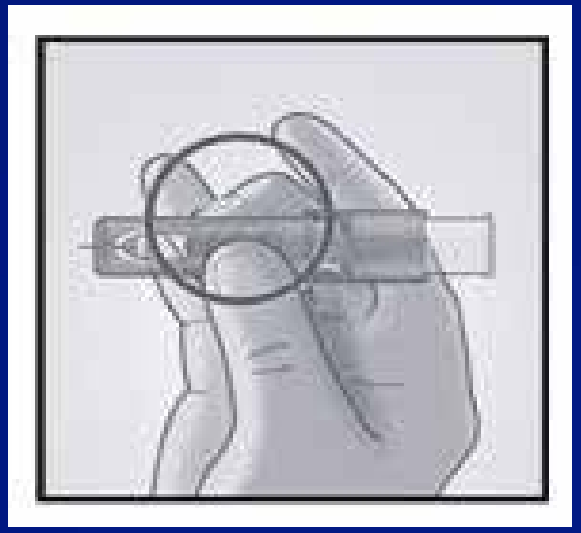
- **Site**
  - Deltoid muscle (upper arm) is preferred
  - Vastus lateralis muscle (anterolateral thigh) may be used
- **Needle gauge: 22- to 25-gauge**
- **Needle length varies related to size of patient**

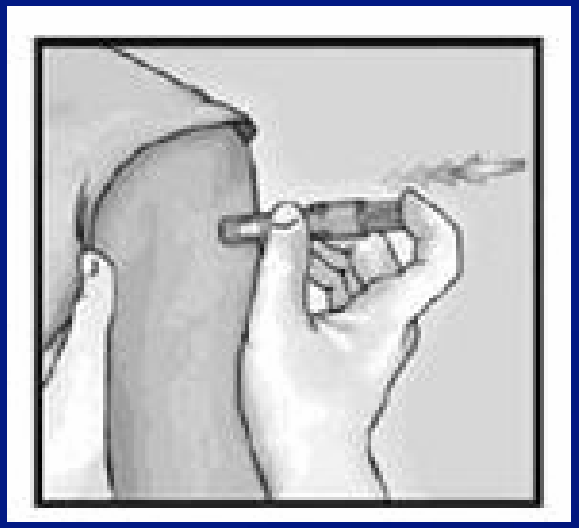




Intradermal (ID) Route

- **Site**
  - Deltoid region of upper arm
- **Needle gauge and length**
  - 30-gauge, microneedle
- **Technique**
  - Hold the syringe between the thumb and the middle finger using a short quick motion insert the needle perpendicular to the skin





Common Errors

Too High

Too Low

Buttock

Multiple Vaccinations

- Separate injections by at least 1 inch, or more if possible
- Use a separate limb for most reactive vaccines (e.g., tetanus toxoid-containing and PCV13), if possible
- Use combination vaccines when appropriate to reduce the number of injections

www.aimtoolkit.org/health-care/vaccine-administration.php

Documentation

- **Required documentation**
  - Date of administration
  - Vaccine manufacturer
  - Vaccine lot number
  - Name & title of person who administered vaccine & address of clinic or facility where permanent record will reside
  - Vaccine Information Statement (VIS)
    - Date printed on the VIS
    - Date VIS given to patient or parent/guardian
- **Best practice documentation**
  - Vaccine type (ACIP abbreviation)
  - Route
  - Dosage (volume
  - Site